REMARKS

Applicant notes with appreciation the interview courteously afforded the undersigned representative of the Applicant on June 16, 2010. The following summarizes the discussion that took place in the interview.

In the Office Action dated April 14, 2010, independent claim 7 was rejected under 35 U.S.C. §102(b) as being anticipated by Bakels et al. This rejection is respectfully traversed for the following reasons.

The pacemaker according to the invention detects arrhythmia, for example, atrial fibrillation, by monitoring intracardiac EGM. In a situation where atrial fibrillation is present, the pacemaker limits atrial distention by increasing the ventricular pacing rate, so that atrial distention decreases, which is observed as an increase in atrial impedance.

The Bakels et al. reference concerns coordinating functioning between the left and right heart of a patient. This is achieved according to Bakels et al. by a pacing system that adapts the pacing of the left heart and the right heart to achieve an optimum synchronization therebetween. This synchronization is monitored by impedance measurements, which the pacemaker uses to adapt the relative timing between left and right pacing. In the present invention, atrial arrhythmia is detected in a conventional manner by detecting the atrial rate. If atrial arrhythmia is present, the ventricular pacing rate is then adapted to limit atrial distention to a predetermined value. Atrial distention (atrial volume) is completely unrelated to stroke volume, and thus an impedance measurement that is directed to detecting stroke volume in a conventional manner would not provide information concerning atrial distention. Moreover, in accordance with the present invention, the atrial distention is monitored

only upon detection of atrial arrhythmia, and in such a situation there is no stroke volume that can be meaningfully defined. The measurement of atrial impedance according to the present invention seeks to determine a volume that is relatively constant, because there are no atrial contractions occurring during atrial fibrillation.

In the interview, the Examiner stated that the Bakels et al. reference appears to detect atrial arrhythmia and, as is conventional, elevate the pacing rate in response to the detection of atrial arrhythmia, and when the arrhythmia episode no longer exists, the pacemaker then reverts to "normal" ventricular pacing at a lower rate. The Examiner stated this appeared to meet the claim language of claim 7.

In response, Applicant's representative stated that the Bakels et al. reference uses the impedance measurement in the conventional manner for detecting stroke volume as an indication as to whether, and to what extent, the heart is beating normally. There is no disclosure in the Bakels et al. reference that monitoring the impedance is used as a basis for determining atrial distention, as in the language of claim 7, and therefore there is no disclosure in the Bakels et al. reference of, after determining, by monitoring the atrial impedance that arrhythmia episode has begun, continuing to monitor the atrial impedance as an indicator of atrial distention and to lower the ventricular pacing rate when the impedance signal indicates that atrial distention is no longer occurring. Since the elevated ventricular pacing rate is used to assist in draining the atrium of excessive blood that pools therein during atrial fibrillation, thereby causing the atrial distention, the ventricular pacing rate is accordingly lowered, by continuing to monitor the atrial impedance as an indicator of atrial distention, when the atrial impedance indicates that atrial distention is no longer occurring. This may or may not coincide with the end of the arrhythmia episode, and

claim 7 does not require that, when it is detected that atrial distention is no longer occurring, the pacemaker reverts to a P-synchronous mode. Claim 7 requires that the atrial impedance be continuously monitored as an indicator of atrial distention, and when the controller determines that atrial distention is no longer occurring, the ventricular pacing rate is then lowered from the previous increased ventricular pacing rate.

Even if the Bakels et al. reference is considered to provide general teachings, as do many other references, to elevate the pacing rate during an arrhythmia episode, and to revert to "normal" pacing at a lower pacing rate when the arrhythmia episode is over, this does not provide a teaching comparable to the language of claim 7. Despite the fact that the Bakels et al. reference, as noted above, does not disclose using the atrial impedance measurement as an indicator of atrial distention, even if the atrial impedance signal were used in Bakels et al. as an indicator of ongoing arrhythmia, this would mean that the Bakels et al. reference reverts to "normal" pacing (i.e., possibly lowering the ventricular pacing rate) when monitoring of the atrial impedance signal indicates that arrhythmia is no longer occurring.

This is not the same as the language of claim 7, which states that the ventricular pacing rate is decreased from its previously increased rate when monitoring of the atrial impedance signal indicates that *atrial distention* is no longer occurring. Claim 7 therefore sets forth a timing of the changes in pacing rate that is not disclosed in Bakels et al.

As also discussed in the interview, a separate argument in support of patentability exists with regard to the language in claim 11 stating that the pulse generator is operated by the controller to vary the delivery rate of pacing pulses to

the ventricle in order to maintain the atrial impedance substantially equal to a reference value. Again, since the atrial impedance is not used in Bakels et al. as an indicator or measurement of atrial distention, there is no disclosure, and no reason, for the pacemaker in Bakels et al. to deliver ventricular pacing pulses to maintain the atrial impedance substantially equal to a reference value.

No agreement as to allowance was reached in the interview, but the Examiner stated she would review the above arguments when formally submitted in a written response, and would reconsider the anticipation rejection based on Bakels et al.

Although not discussed in the interview, claims 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bakels et al., and claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bakels et al. in view of Mann. The above arguments concerning the anticipation rejection based on Bakels et al. are applicable to these rejections as well. In view of the lack of any teaching or suggestion in Bakels et al. to make use of the atrial impedance signal as an indicator of atrial distention, and to then time ventricular pacing based on continued monitoring of atrial distention via the atrial impedance signal, modification of the Bakels et al. reference, by itself or in view of the teachings of Mann, in order to arrive at the subject matter of any claims 9 through 12 would not have been obvious to a person of ordinary skill in the field of designing carding pacemakers.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

(Reg. 28,982)
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